IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

JOSEPH BLACKBURN, SR.,

Plaintiff,

ENTERED

AUG 2 4 2005

U.S. DISTRICT COURT
ELKINS, WV 26241

CIVIL ACTION NO. 2:04CV65 (Judge Maxwell)

HOECHST MARION ROUSELL, INC.; and LEDERLE, INC.,

Defendants.

ORDER

I. PROCEDURAL HISTORY

On September 13, 2004, the *pro se* plaintiff, Joseph Blackburn, Sr., filed a products liability action against the above-named defendants pursuant to 28 U.S.C. §1332 seeking compensatory and punitive damages. On January 12, 2005, counsel for Wyeth, as Wyeth Pharmaceuticals, filed a Motion to Dismiss the Plaintiff's Complaint in the above-styled case pursuant to Rules 12(b)(2) and 8(c) of the Federal Rules of Civil Procedure.

On January 31, 2005, the Court issued a Roseboro² notice advising the plaintiff of his right to respond to the motion to dismiss.

On February 1, 2005, Aventis Pharmaceutical, Inc., ["Aventis"], as the successor in interest of Hoechst Marion Roussel, Inc., filed a Motion to Dismiss, and Alternative Motion for Summary

v.

¹Counsel states that the complaint was served on Wyeth Pharmaceuticals, an unincorporated division of Wyeth, improperly designated as Lederle, Inc., a non-entity.

²Roseboro v. Garrison, 528 F.2d 309, 310 (4th Cir. 1975).

Judgment pursuant to Rules 12(b)(6) and 56 of the Federal Rules of Civil Procedure.

On February 23, 2005, the plaintiff filed (1) a Motion to Amend Complaint and Join Real Party in Interest, Wyeth; (2) a Motion to Amend Complaint and Join Real Party in Interest, Aventis Pharmaceutical, Inc.; and (3) a Response to the Motion to Dismiss filed by Wyeth and the Motion to Dismiss or in the Alternative Motion for Summary Judgment filed by Aventis. On March 7, 2005, Aventis filed a reply to the plaintiff's response to its motion to dismiss. On April 7, 2005, the plaintiff filed a reply to Aventis' reply. On April 19, 2005, Aventis filed a sur-reply. On May 18, 2005, the plaintiff filed a response to the sur-reply of Aventis.

The matter has been fully briefed and is ripe for review.

II. PLAINTIFF'S ALLEGATIONS

The plaintiff asserts that Lederle is the "patent holder, manufacturer, supplier, and professional vendor," of the drug Pyrazinamide and that Hoechst Marion Roussel, Inc. is the "patent holder, manufacturer, supplier and professional vendor" of Rifampin. He alleges that Dr. Walker of the Randolph-Elkins County Health Department provided him with doses of Pyrazinamide and Rifampin in combination for numerous years to treat tuberculosis.³ According to the plaintiff, he suffers from a serious liver condition and related complications and has been unable to be gainfully employed or to "lead a normal product (sic) life" as a result of taking Pyrazinamide and Rifampin in combination. Complaint ¶15. The plaintiff asserts that "[t]he defendants at all times were aware of the danger of proscribing rifampin and pyrazinamide as a treatment together." Complaint ¶4. He further alleges that "[i]n fact contrary to testing that the defendants had performed which clearly

³The plaintiff has been treated for tuberculosis since 1967. He started taking the drugs in question in 1975.

proved that rifampin and pyrazinamide administered jointly resulted in serious liver damage, terminal liver damage. Regardless of this knowledge the defendants encouraged the joint use of the two drugs in combination." Complaint ¶5.

The plaintiff further alleges that, while Lederle and Hoechst Marion Roussel knew of the dangers of using the two drugs in combination, they failed to advise health care providers of the necessity of regular liver screenings and testing; did not disclose their complete testing results; did not provide proper label precautions; and did not warn of the dangers of taking the drugs in combination while using alcohol excessively.

III. MOTIONS TO DISMISS⁴

A. Motion to Dismiss of Wyeth

Wyeth asserts that Lederle, Inc., is a non-existent company. Wyeth further asserts that on August 5, 2002, the plaintiff filed a complaint in this Court against the United States Department of Health and Human Services (civil action number 2:02cv57) wherein he alleged that he had previously taken Pyrazinamide and Rifampin and that he had been informed in 1983, that these two drugs could kill him. Additionally, Wyeth points out that the plaintiff attached to his prior complaint a medical progress note dated September 16, 1993, which indicated that he was told by a physician that Isoniazid and Rifampin could "kill his liver." The complaint in the plaintiff's prior civil action

⁴The plaintiff asserts that pursuant to Rule 8(d) of the Federal Rules of Civil Procedure the defendants have failed to respond to or deny any of his averments and that, accordingly, they are admitting to said averments. However, the defendants may file a motion to dismiss before filing an answer. See Rule 12 of the Federal Rules of Civil Procedure. Morever, Adventis filed a Protective Answer on January 12, 2005 and denied the plaintiff's averments.

was dismissed on April 4, 2004. 5

Wyeth asserts that the current action should be dismissed as being barred by the statute of limitations. Wyeth further asserts that the plaintiff's complaint "should be dismissed pursuant to Rule 12(b)(2) due to (1) lack of jurisdiction over the subject matter, (2) lack of jurisdiction over the person/defendants, (3) improper venue, (4) insufficiency of process, (5) insufficiency of service of process, (6) failure to state a claim upon which relief can be granted and (7) failure to join a party under Rule 19 of the Federal Rules of Civil Procedure." Additionally, Wyeth asserts that the complaint should be dismissed pursuant to Rule 8(c) of the Federal Rules of Civil Procedure "on the basis of, but not limited to, accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, statute of limitations, waiver and other matters which constitute an avoidance."

B. Motion to Dismiss/Motion for Summary Judgment of Aventis

Aventis moves to dismiss the case or, in the alternative, moves for summary judgment pursuant to Rule 12(b)(6) and Rule 56 of the Federal Rules of Civil Procedure and argues that the complaint is barred by the statute of limitations. Aventis argues that the claim is barred by the statute of limitations since the plaintiff knew in 1993, that he had liver damage and that his medications could result in liver damage. Aventis further points out that the plaintiff filed suit in

⁵Case number 2:02cv57 was dismissed by Order entered April 4, 2004. The plaintiff's claims against the United States Department of Health and Human Services were dismissed because the plaintiff had not exhausted his administrative remedies regarding his federal tort claim action against that entity. Once the plaintiff's claims against the United States Department of Health and Human Services were dismissed, the Court no longer had jurisdiction over the remaining defendants, all of which were residents of the State of West Virginia.

2002 (civil action no. 2:02-cv-57), regarding the alleged side effects of the drugs. Despite the fact that neither Aventis nor Wyeth were named as parties in that action, the plaintiff, nonetheless, sent Aventis communication regarding his suit and indicated that he knew of Aventis' relationship with Rifampin.

IV. STANDARD OF REVIEW

Rule 8(c) of the Federal Rules of Civil Procedure provides as follows:

(c) Affirmative Defenses. In pleading to a preceding pleading, a party shall set forth affirmatively accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, statute of limitations, waiver, and any other matter constituting an avoidance or affirmative defense. When a party has mistakenly designated a defense as a counterclaim or a counterclaim as a defense, the court on terms, if justice so requires, shall treat the pleading as if there had been a proper designation.

A complaint may be dismissed under Rule 12(b)(2) for lack of jurisdiction over the person.

The Court may take judicial notice of the plaintiff's prior civil action and the information contained in its record. <u>Johnson v. Commissioner, I.R.S., U.S. Dept. of Treasury</u>, 2004 WL 1729451, *2 (D.S.C.) (D.S.C. 2004); <u>See also Ramirez v. Wal-Mart Stores, Inc.</u>, 192 F.R.D. 303, 304 (D.N.M. 2000).

In ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must accept as true all well-pleaded material factual allegations. <u>Franks v. Ross</u>, 313 F. 3d 184, 192 (4th Cir. 2002). Furthermore, dismissal for failure to state a claim is properly granted where, assuming the facts alleged in the complaint to be true, and construing the allegations in the light most favorable to the plaintiff, it is clear, as a matter of law, that no relief could be granted under any set of facts that could

be proved consistent with the allegations of the complaint. <u>Hishon v. King & Spalding</u>, 467 U.S. 69, 73 (1984); Conley v. Gibson, 355 U.S.41, 45-46 (1957).

"The raising of the statute of limitations as a bar to plaintiffs' cause of action constitutes an affirmative defense and may be raised by motion pursuant to Fed.R.Civ.P.12(b)(6), if the time bar is apparent on the face of the complaint." <u>Dean v. Pilgrim's Pride Corp.</u>, 395 F.3d 471, 474 (4th Cir. 2005)(internal citations omitted).

In the instant case, Aventis has submitted numerous documents from the plaintiff's prior civil action. Pursuant to Rule 12(b), the Court finds that the motion filed by Aventis should be considered as a motion for summary judgment.

Rule 12(b) states, in pertinent part:

If, on a motion asserting the defense numbered (6) to dismiss for failure of the pleading to state a claim upon which relief can be granted, matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.

"When a party is aware that material outside the pleadings is before the court, the party is on notice that a Rule 12(b)(6) motion may be treated as a motion for summary judgment." Gay v. Wall, 761 F.2d 175, 177 (4th 1985). See Laughlin v. Metropolitan Washington Airports Auth., 149 F. 3d 253, 261 (4th Cir. 1998).

From the text of Rule 56(c) of the Federal Rules of Civil Procedure, it is clear that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(c).

Motions for summary judgment impose a difficult standard on the moving party; for, it must be obvious that no rational trier of fact could find for the nonmoving party. Miller v. Federal Deposit Ins. Corp., 906 F.2d 972, 974 (4th Cir. 1990).

However, the "mere existence of a scintilla of evidence" favoring the nonmoving party will not prevent entry of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). To withstand such a motion, the nonmoving party must offer evidence from which a "fair-minded jury could return a verdict for the [party]." Id. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Felty v. Graves-Humphreys Co., 818 F.2d 1126, 1128 (4th Cir. 1987). Such evidence must consist of facts which are material, meaning that the facts might affect the outcome of the suit under applicable law, as well as genuine, meaning that they create fair doubt rather than encourage mere speculation. Anderson, 477 U.S. at 248. It is well recognized that any permissible inferences to be drawn from the underlying facts must be viewed in the light most favorable to the party opposing the motion. Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986).

V. ANALYSIS

While the plaintiff indicates in his complaint that this is a products liability action, he appears in his response to also be attempting to raise claims under the Commerce Clause and the Federal Food, Drug and Cosmetic Act. However, there is no private cause of action for damages under the Commerce Clause. Washington v. United States Tennis Association, 290 F. Supp.2d 323 (E.D. N.Y. 2003). Further, there is no private cause of action for damages under the Federal Food, Drug and Cosmetic Act. Merrell Dow Pharmaceuticals, Inc., v. Thompson, 478 U.S. 804 (1986). Thus, the

only action at issue in the matter now before the Court is the products liability action which the defendants assert is barred by the statute of limitations.

Because this action is before this Court on the basis of diversity jurisdiction, the Court must apply the substantive law of West Virginia and West Virginia's statute of limitations. See Erie Railroad Co. v. Tompkins, 304 U.S. 64, 78 (1938) and Guaranty Trust Co. v. York. 326 U.S. 99, 110 (1945); see also Hamilton v. Pilgrim's Pride Corp., 314 F.Supp.2d 630, 635 (N.D.W.Va. 2004).

The statute of limitations for a products liability claim in West Virginia is two years. W. Va. Code §55-2-12. See also Hickman v. Grover, 358 S.E. 2d 810 (W.Va. 1987). "In products liability cases, the statute of limitations begins to run when the plaintiff knows, or by the exercise of reasonable diligence should know, (1) that he has been injured, (2) the identity of the maker of the product, and (3) that the product had a causal relation to his injury." Hickman, 358 S.E.2d at 813.

The plaintiff alleges that his complaint is not barred by the statute of limitations because "[r]egardless of Dr. Walker's statement; he and that same health care provider prescribed additional dosages of the drugs in combination free to the plaintiff. Certainly, the plaintiff had every reason to believe that the continued prescription of the drugs represented no danger to his health." (Doc. #15 at 3). He further alleges that he was not aware of the cause of his liver damage. (Id. at 4). The plaintiff further argues that "on August 3, 2004, the Center for Disease Control (CDC), after FDA recommendations and deaths of individuals; issued an advisory warning against the treatment of a combination of Rifampin and Pyrazinamide in the treatment of latent tuberculosis infection." (Id.). He states that "[w]hen Plaintiff learned that the manfacture[r]s were responsible for providing improper information as to the use of their drugs the Plaintiff amended his Complaint." (Id. at 5). According to the plaintiff, the statute of limitations began on March 14, 2003, the date the

Amendment was filed in the case number 2:02cv57. (Id. at 14).

However, on August 5, 2002, the plaintiff filed a complaint against various medical providers, and the United States Department of Health and Human Services and the West Virginia Department of Health and Human Services for prescribing Rifampin and Pyrazinamide in a combination which was known to cause liver damage. (Case no. 2:02cv57). Lederle, Hoescht Marion Roussel, Adventis, and Wyeth were not added as defendants in case number 2:02cv57. In his complaint in case number 2:02cv57, the plaintiff stated in paragraph 35 as follows: "In 1983, the plaintiff was informed that Rifampin and Pyrazinamide could kill him. (A-87)." Attachment A-87 is a document titled "Progress Notes" and is dated September 16, 1993. The note states as follows:

Mr. Blackburn's wife came to the health dept. on this date, with two prescriptions one for INH and one for Rifampin written by Dr. G. Giccirilli. During the course of my conversation with Mrs. Blackburn she stated that her husband has cirrosis of the liver and that his doctor told him that these medications could "kill his liver." I placed a call to Dr. Walker's office re these drugs and this man's present physical condition. Dr. Walker's office advises that these drugs be held until a positive bar specimen is obtained.

In paragraph 36 of his complaint in case number 2:02cv57, the plaintiff stated that "the Plaintiff's condition is terminal and doctors have advised him that the drugs Rifampin and Pyrazinamide have destroyed his liver."

Accordingly, the Court takes judicial notice of the complaint in the prior action and finds that the instant complaint is untimely. The plaintiff admitted in his prior complaint that he knew in 1983 that Rifampin and Pyrazinamide could "kill him." Further, he referenced a 1993 progress note which reveals that he knew his medication could "kill him." In fact, he attached the same progress note to the instant complaint. Thus, the face of the instant complaint reveals that as of September 1993, the

plaintiff had liver damage and was warned that the medication he was taking for tuberculosis could cause such damage. Accordingly, for more than two years prior to the filing of the instant complaint, the plaintiff knew or should have known of his liver damage that could have been caused by the use of Rifampin and Pyrazinamide in combination. The Court's finding is, in fact, further supported by the fact that the instant complaint was filed more than two years after the plaintiff filed civil action number 2:02cv57, wherein he alleged that he had sustained liver damage caused by the use of the two drugs in combination. The basis for the filing of the plaintiff's former action conclusively demonstrates that the instant action is untimely.

Lastly, although the plaintiff asserts that the statute of limitations should begin on March 14, 2003, the date he filed a motion to amend his complaint to include Wyeth and Aventis in civil action 2:02cv57, the Court finds that, through the exercise of reasonable diligence, the plaintiff could have discovered earlier the names of the manufacturers of Rifampin and Pyrazinamide.

For all of the foregoing reasons, the Court finds that the plaintiff has failed to state a claim upon which relief may be granted and that there is no genuine issue of material fact that the plaintiff's complaint is untimely. Accordingly, it is

ORDERED that the Motion to Dismiss filed by Wyeth is GRANTED. It is further

ORDERED that the Motion to Dismiss filed by Aventis is treated as a Motion for Summary

Judgment and is GRANTED. It is further

ORDERED that the plaintiff's complaint is **DISMISSED WITH PREJUDICE** as being untimely and that the plaintiff's motions to amend are **DENIED**.

It is so **ORDERED**.

The Clerk is DIRECTED to transmit copies of this Order to the *pro se* plaintiff and counsel for the defendants.

ENTER: August **24**, 2005

UNITED STATES DISTRICT JUDGE